

REMARKS

Applicant's attorneys submitted an amendment in response to the Office Action dated March 26, 2002 on June 26, 2002. It has since come to the attention of said attorneys that the Marked-Up Version of the Claims submitted on June 26, 2002 did not accurately reflect the changes made. In addition, Applicant's attorneys have noted a few typographical errors and errors in claim dependency in the claims submitted on June 26, 2002.

In order to accurately reflect the changes made and correct the errors in the claims, Applicant's attorneys submit herewith a clean version of the claims and a marked-up version of the claims to replace the submission of June 26, 2002.

This version corrects the following errors that appeared in the claims submitted on June 26, 2002:

Amended claim 1, line 8 change "third" to "second" and line 12 omit "conventional"

New claim 17, line 8 change "third" to "second" and line 12 omit "conventional"

New claim 18, line 5 change "second" to "third"

New claim 19, line 16 omit "conventional"

This version also corrects four dependency errors in new claims 8-11. Claim 9 as submitted on June 26, 2002 is now claim 8 with previously submitted claim 8 being corrected to reflect dependency on what is now new claim 8 instead of claim 7. Claims 10 and 11 as submitted on June 26, 2002 have been changed to reflect their dependency on claim 8 ,instead of claim 9.

The Version with Markings to Show Changes Made submitted herewith corrects errors in failing to properly underline text that was added and failing to bracket omitted text in the Version with Markings to Show Changes Made submitted on June 26, 2002 and accurately shows the changes between the claims addressed by the Examiner in the Office Action of March 26, 2002 and the amended claims submitted in response to that Action.

Applicant's attorneys have also noticed that the changes in the substitute specification submitted on June 26, 2002 were not accurately reflected by the marked-up version of the specification also submitted. Changes were made to the specification in the form of replacement of double dashes (--) with single dashes (-) and addition or deletion of spaces between words and within tables. Three words were also changed: on page 1, line 17 "Nowadays" was omitted and "blood" was capitalized and on page 5, line 4 "than" was changed to "that."

No new material is added in this submission.

CONCLUSION

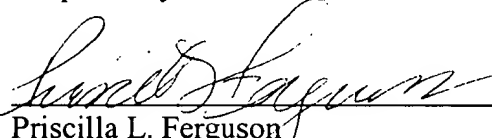
In view of the foregoing amendment and remarks, Applicant submits that all of the claims now present are allowable, and withdrawal of the rejections and a Notice of Allowance are courteously solicited.

If any impediment to the allowance of the claims remains after consideration of this amendment, and such impediment could be alleviated during a telephone interview, the Examiner is invited to telephone the undersigned at (214) 969-4657 so that such issues may be resolved as expeditiously as possible.

If any applicable fee or refund has been overlooked, the Commissioner is hereby authorized to charge any fee or credit any refund to the deposit account of Akin, Gump, Strauss, Hauer & Feld, L.L.P., No. 01-0657.

Respectfully Submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. (Twice Amended) **An L-arginine free** [A] pharmaceutical composition comprising: [1.5--6.9 % (w/v) of one or more substances selected from]

a first substance comprising sodium chloride in an amount between about 1.5% and 6.9% (w/v);

5 **a second substance comprising at least one of** [sodium chloride, sodium bicarbonate, potassium chloride, magnesium sulfate, calcium chloride, calcium gluconate, calcium lactate, sodium lactate, sodium acetate and Tris (Hydroxy methyl) aminomethane, and 3 ~ 18 % (w/v) of one or more substances selected from] hydroxyethyl_starch, dextran, carboxymethyl_starch, polyvinyl [--] pyrrolidone (PVP),
10 gelatin derivatives, condensed glucose, glucose, fructose, lactose, glycerin, xylitol, sodium alginate, N-[-]2-hydroxypropylacrylamide, ethylene epoxide[-], polypropylene glycol, pectin, and pentahydroxyethyl_starch[; as well as the remainder of conventional injections, as long as sodium chloride is not less than 1. 5 % (w/v), and the concentration of sodium ion is not more than that of in a 6.9 % (w/v) sodium chloride solution or
15 equivalent], **wherein said second substance is present in an amount between about 3 and 18 % total (w/v); and**

an injection comprising at least one of water, physiological saline, balanced buffers, glucose solution, sodium lactate solution, sodium acetate solution, Tris solution, and glucose and sodium chloride solution, wherein said injection is present
20 **in an amount between about 75.1% and 95.5% total (w/v).**

2. (Amended) The pharmaceutical composition of Claim 1, wherein [the composition contains 4.2 ± 0.2 g] **said first substance comprises** sodium chloride **in an amount between about 2.5 and about 2.7 g;** and

said second substance comprises [7.6 ± 0.6 g] hydroxyethyl_starch **in an amount**
5 **between about 7.0 g and about 8.2 g** per 100 mL.

Please cancel claim 3 without disclaimer or prejudice.

4. (Thrice Amended) The pharmaceutical composition of Claim 1, wherein said **second substance comprises** hydroxyethyl starch, [contains] at least 10% [hydroxyethyl starch] **of which has** [with] a molecular weight of **about** 25,000-[-]45,000 atomic mass units.

5. (Twice Amended) The pharmaceutical composition of Claim 1, wherein said **second substance comprises** gelatin derivatives ha[s]**ving** a molecular weight of **about** 20,000-[-]35,000 atomic mass units, **said gelatin derivatives being** [and are] selected from **at least one of** urea[--], conjugated gelatin, modified liquid gelatin, oxidized polygelatin and degraded gelatin polypeptide.

6. (Twice Amended) The pharmaceutical composition of Claim 1, wherein said **second substance comprises at least one of** dextran ha[s]**ving** a molecular weight of **about** 40,000-[-]230,000 atomic mass units, [said] carboxymethylstarch ha[s]**ving** a molecular weight of **about** 30,000-[-]80,000 atomic mass units, [said] PVP ha[s]**ving** a molecular weight of **about** 5,000-[-]700,000 atomic mass units, [said] condensed glucose ha[s]**ving** a molecular weight of **about** 8,000-12,000 atomic mass units, [said] sodium alginate ha[s]**ving** a molecular weight of **about** 20,000-[-]26,000 atomic mass units, [said] pectin ha[s]**ving** a molecular weight of **about** 20,000-40,000 atomic mass units, [said] and [said] pentahydroxyethyl starch ha[s]**ving** a molecular weight of about 264,000 atomic mass units.

7. (Twice Amended) A method for preparing the pharmaceutical composition of Claim 1, comprising:

dissolving [3--18g of one or more substances selected from hydroxyethylstarch, dextran, carboxymethylstarch, PVP, gelatin derivatives, condensed glucose, glucose, fructose, lactose, glycerin, xylitol, sodium alginate, N--2--hydroxypropylacrylamide, ethylene epoxide-

polypropylene glycol, pectin, and pentahydroxyethylstarch,] an amount between about 3 g and 18 g of said second substance in a total of 100 ml of [one] said injection; [or mixture of several injections selected from water, physiological saline, balanced buffers, glucose solution, sodium lactate solution, sodium acetate solution, Tris solution, and glucose and sodium chloride solution]

adding 1.5 g [sodium chloride

and 0—5.4g of one or more substances selected from sodium chloride, sodium bicarbonate, potassium chloride, magnesium sulfate, calcium chloride, calcium gluconate, calcium lactate, sodium lactate, sodium acetate, and Tris] of said first substance; and

[mixing to dissolution to obtain said pharmaceutical composition.] mixing said conventional injection to dissolve said first and second substances therein.

8. The pharmaceutical composition of Claim 1 further comprising:

a third substance comprising at least one of sodium bicarbonate, potassium chloride, magnesium sulfate, calcium chloride, calcium gluconate, calcium lactate, sodium lactate, sodium acetate and Tris (Hydroxy methyl) aminomethane,

wherein the total sodium ion concentration based on said first and third substances does not exceed an equivalent sodium ion concentration in a 6.9 % (w/v) sodium chloride solution.

9. The method for preparing the pharmaceutical composition of Claim 8 comprising:

dissolving an amount between about 3 g and 18 g of said second substance in a total of 100 ml of said injection;

adding 1.5 g of said first substance;

5 adding an amount between 0 and about 5.4 g of said third substance, such that the total sodium ion concentration based on said first and third substances does not exceed an equivalent sodium ion concentration in a 6.9 % (w/v) sodium chloride solution; and

 mixing said injection to dissolve said first, second, and third substances therein.

10. The pharmaceutical composition of Claim 8, wherein

said first substance comprises sodium chloride in an amount of about 1.5 g;

said second substance comprises hydroxyethyl starch in an amount of about 3 g and dextran in an amount of about 9 g;

5 said third substance comprises sodium bicarbonate in an amount of about 3.4 g; and

said injection comprises physiological saline.

11. The pharmaceutical composition of Claim 8, wherein

said first substance comprises sodium chloride in an amount of about 2.0 g

said second substance comprises PVP in an amount of about 12 g;

said third substance comprises sodium acetate in an amount of about 4 g;

5 and

said injection comprises a 10% glucose solution.

12. The pharmaceutical composition of Claim 1, wherein

said first substance comprises sodium chloride in an amount of about 2.7 g;

said second substance comprises hydroxyethyl starch in an amount of about 7.6 g; and

said injection comprises water.

13. The pharmaceutical composition of Claim 1, wherein

said first substance comprises sodium chloride in an amount of about 1.5 g;

said second substance comprises sodium alginate in an amount of about 18 g;
and

said injection comprises water.

14. The pharmaceutical composition of Claim 1, wherein

said first substance comprises sodium chloride in an amount of about 4.4 g;

said second substance comprises condensed glucose in an amount of about 7 g and N-2-hydroxypropylacrylamide in an amount of about 2 g; and

said injection comprises water.

15. The pharmaceutical composition of Claim 1, wherein

said first substance comprises sodium chloride in an amount of about 4.8 g;

said second substance comprises fructose in an amount of about 5 g and xylitol in an amount of about 4 g; and

said injection comprises water.

16. The pharmaceutical composition of Claim 1, wherein

said first substance comprises sodium chloride in an amount of about 6.0 g;

said second substance comprises glycerin in an amount of about 2 g and lactose in an amount of about 5 g; and

said injection comprises water.

17. The pharmaceutical composition of Claim 1 comprising:

a first substance comprising sodium chloride in an amount between about 1.5% and 5.9%(w/v);

a second substance comprising at least one of hydroxyethyl starch, dextran, carboxymethyl starch, polyvinyl pyrrolidone (PVP), gelatin derivatives, condensed glucose, glucose, fructose, lactose, glycerin, xylitol, sodium alginate, N-2-hydroxypropylacrylamide, ethylene epoxide, polypropylene glycol, pectin, and pentahydroxyethyl starch, wherein said second substance is present in an amount between about 3 and 18 % total (w/v); and

an injection comprising at least one of water, physiological saline, balanced buffers, glucose solution, sodium lactate solution, sodium acetate solution, Tris solution, and glucose and sodium chloride solution, wherein said injection is present in an amount between about 76.1% and 95.5% total (w/v),

18. The pharmaceutical composition of Claim 17 further comprising:

a third substance comprising at least one of sodium bicarbonate, potassium chloride, magnesium sulfate, calcium chloride, calcium gluconate, calcium lactate, sodium lactate, sodium acetate and Tris (Hydroxy methyl) aminomethane,

5 **wherein the total sodium ion concentration based on said first and third substances does not exceed an equivalent sodium ion concentration in a 5.9 % (w/v) sodium chloride solution.**

19. A pharmaceutical composition consisting essentially of:

a first substance consisting essentially of sodium chloride in an amount not less than about 1.5% (w/v);

5 **a second substance comprising at least one of sodium bicarbonate, potassium chloride, magnesium sulfate, calcium chloride, calcium gluconate, calcium lactate, sodium lactate, sodium acetate and Tris (Hydroxy methyl) aminomethane, wherein said second substance is present in an amount between about 0 and 5.4% (w/v).**

10 **a third substance consisting essentially of at least one of hydroxyethyl starch, dextran, carboxymethyl starch, polyvinyl pyrrolidone (PVP), gelatin derivatives, condensed glucose, glucose, fructose, lactose, glycerin, xylitol, sodium alginate, N-2-hydroxypropylacrylamide, ethylene epoxide, polypropylene glycol, pectin, and pentahydroxyethyl starch, wherein said third substance is present in an amount between about 3 and 18 % total (w/v); and**

15 **an injection consisting essentially of at least one of water, physiological saline, balanced buffers, glucose solution, sodium lactate solution, sodium acetate solution, Tris solution, and glucose and sodium chloride solution, wherein said injection is present in an amount between about 75.1% and 95.5% total (w/v),**

20

wherein the total sodium ion concentration based on said first and second substances does not exceed an equivalent sodium ion concentration in a 6.9 % (w/v) sodium chloride solution.